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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,871	08/20/2003	Mary Anne Nelson	310.00120120 (MC-248.CIP1	5206

22506 7590 07/25/2006

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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,871	NELSON ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-102* is/are pending in the application.

4a) Of the above claim(s) *38-102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Claims 1-37 in the reply filed on 3 May 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 38-102 are withdrawn from consideration.

Claims 1-37 are under prosecution.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: METHODS FOR COVALENTLY ATTACHING POLYPEPTIDES TO SUBSTRATES.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 is indefinite because the recitation "said thiolate diazonium group" lacks proper antecedent basis in Claim 34. It is suggested the claim be amended to provide proper antecedent basis e.g. change the dependency to Claim 36.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1,19, 30, 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Currell et al (J. Applied Polymer Sci, 1997, 66: 1433-1438).

Regarding Claim 1, Currell et al disclose a microarray (i.e. resin support, Abstract)comprising a diazotized tether group bound to a substrate and at least one polypeptide covalently bound to the tether (Scheme 3, page 1436). It is noted that the instant specification defines a microarray as "a device that employs the attachment of biomolecules, such as polypeptides, to a substrate." (¶ 34). Currell et al teaches a device to which polypeptides are attached (Abstract and Scheme 3) and therefore anticipates the claimed invention.

Regarding Claim 19, Currell et al disclose the substrate is a polymer (i.e. PVA, page 1434, last paragraph).

Regarding Claim 30, Currell et al disclose the polypeptide comprises a plurality of polypeptides (page 1435, first full paragraph).

Regarding Claim 32, Currell et al disclose the polypeptide is a protein i.e. BSA and β-glucosidase, page 1437, first full paragraph).

7. Claims 1, 19, 30-33 and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark (U.S. Patent No. 5,484,852, issued 16 January 1996).

Regarding Claim 1, Clark discloses a microarray (i.e. solid support, Abstract) comprising a diazotized tether group bound to a substrate and at least one polypeptide covalently bound to the tether (Column 10, lines 5-24). It is noted that the instant specification defines a microarray as "a device that employs the attachment of biomolecules, such as polypeptides, to a substrate." (¶ 34). Clark teaches a device to which polypeptides are attached (Abstract and Scheme 3) and therefore anticipates the claimed invention.

Regarding Claim 19, Clark discloses the substrate is a polymer (i.e. polystyrene, Column 10, lines 7-8).

Regarding Claim 20, Clark discloses the substrate is a plastic (i.e. polystyrene, Column 10, lines 7-8).

Regarding Claim 30, Clark discloses the polypeptide comprises a plurality of polypeptides (Column 10, lines 20-22).

Regarding Claim 31, Clark discloses the polypeptide comprises a plurality of different polypeptides (Column 9, lines 15-37).

Regarding Claim 32, Clark discloses the polypeptide is a protein (Column 10, lines 21-24).

Regarding Claim 33, Clark discloses the substrate having a thickness of "approximately" 1mm (i.e. 100Å, Table 1and Column 10, lines 7-8).

Regarding Claim 36, Clark discloses the tether group as a thiolate diazonium (Column 5, lines 10-12 and 34-37).

Regarding Claim 37, Clark discloses the thiolate diazonium comprises p-diaxoinumthiophenol salt (Column 5, lines 10-37).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 2-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark (U.S. Patent No. 5,484,852, issued 16 January 1996) in view of Fancy et al (Chemistry & Biology, 1996, 3(7): 551-559) and/or Currell et al (J. Applied Polymer Sci, 1997, 66: 1433-1438).

Regarding Claims 2-8, Clark discloses a microarray (i.e. solid support, Abstract) comprising a diazotized tether group bound to a substrate and at least one polypeptide covalently bound to the tether (Column 10, lines 5-24). It is noted that the instant specification defines a microarray as "a device that employs the attachment of biomolecules, such as polypeptides, to a substrate." (¶ 34). Clark teaches a device to which polypeptides are attached (Abstract and Scheme 3) and therefore anticipates the claimed invention.

Clark further teaches the support wherein the protein is linked to the support via long or short bridge as known in the art and comprising poly amino acids (Column 5, lines 15-18, 38-48) but the reference does not teach specific amino acids e.g. histidine.

However, covalent linkage of a protein to a solid support via a histidine tag at the terminus of the protein was well known in the art at the time the claimed invention was made as taught by Fancy et al and Currell et al. Currell et al teach a similar protein immobilization wherein the protein is covalently linked to the support through a diazo-histidine bridge (Abstract). Currell et al further teach the immobilization wherein the diazo-histidine bridge attaches the protein at positions outside the active site (page 1437, first full paragraph) which suggests the coupling is also at internal histidine residues of the protein. Currell et al teach the immobilization is fast and stable under operating conditions without loss of function thereby providing a "choice" method of immobilization (page 1437, right column). It would

have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the diazo-histindine immobilization of Currell et al to the protein immobilization of Clark. One of ordinary skill in the art would have been motivated to do so based on the suggested polyaminoacid bridge of Clark and further for the expected benefit of fast immobilization that is stable under operating conditions without loss of function thereby providing a "choice" method of immobilization as taught by Currell et al (page 1437, right column).

Fancy et al also teach an immobilized protein wherein the protein comprises 6 histidine residues (i.e. histidine tags) positioned at the terminus of the protein (page 552). Fancy et al teach that the tags provide for fast and efficient separation of proteins without loss of function (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the histidine tag taught by Fancy et al to the protein immobilization of Clark. One of ordinary skill in the art would have been motivated to do so based on the suggested polyaminoacid bridge of Clark and further for the expected benefit of fast and efficient separation of proteins without loss of function as taught by Fancy et al (Abstract).

It would have been further obvious to modify the polyaminoacid bridge of Clark by using a bridge of 20 histidine residues based on the "long" bridge suggestion of Clark wherein the length of the bridge is selected based on intended use (Column 5, lines 15-18).

10. Claims 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark (U.S. Patent No. 5,484,852, issued 16 January 1996) in view of Fancy et al (Chemistry & Biology, 1996, 3(7): 551-559) and Currell et al (J. Applied Polymer Sci, 1997, 66: 1433-1438).

Regarding Claim 9-15, Clark discloses a microarray (i.e. solid support, Abstract) comprising a diazotized tether group bound to a substrate and at least one polypeptide covalently bound to the tether (Column 10, lines 5-24). It is noted that the instant specification defines a microarray as "a device that employs the attachment of biomolecules, such as polypeptides, to a substrate." (¶ 34). Clark teaches a device to which polypeptides are attached (Abstract and Scheme 3) and therefore anticipates the claimed invention.

Clark further teaches the support wherein the protein is linked to the support via long or short bridge as known in the art and specifically exemplifies protein immobilization via a tyrosine of the protein (Column 10, lines 20-24) but the reference is silent regarding the number and/or position of the tyrosine residues within the protein.

However, covalent linkage of a protein to a solid support via a tyrosine tag at the terminus of the protein was well known in the art at the time the claimed invention was made as taught by Currell et al. Currell et al teach a similar protein immobilization wherein the protein is covalently linked to the support through a diazo-tyrosine bridge (Abstract). Currell et al further teach the immobilization wherein the diazo-tyrosine bridge attaches the protein at positions outside the active site (page 1437, first full paragraph) which suggests the coupling is also at internal histidine residues of the protein. Currell et al teach the immobilization is fast and stable under operating conditions without loss of function thereby providing a "choice" method of immobilization (page 1437, right column). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the diazo-tyrosine immobilization of Currell et al to the protein immobilization of Clark. One of ordinary skill in the art would have been motivated to do so based on the suggested polyaminoacid bridge of Clark and further for the expected benefit of fast immobilization that is stable under operating conditions without loss of function thereby providing a "choice" method of immobilization as taught by Currell et al (page 1437, right column). It would have been further obvious to modify the polyaminoacid bridge of Clark by using a bridge containing 6 or 20 tyrosine

residues based on the "short or long" bridge suggestion of Clark wherein the length of the bridge is selected based on intended use (Column 5, lines 15-18).

11. Claims 16-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark (U.S. Patent No. 5,484,852, issued 16 January 1996) in view of Blackburn (U.S. Patent No. 6,875,619, filed 17 May 2001).

Regarding Claims 16-29, Clark discloses a microarray (i.e. solid support, Abstract) comprising a diazotized tether group bound to a substrate and at least one polypeptide covalently bound to the tether (Column 10, lines 5-24). It is noted that the instant specification defines a microarray as "a device that employs the attachment of biomolecules, such as polypeptides, to a substrate." (¶ 34). Clark exemplifies a polystyrene microtiter plate (Column 10, lines 7-8) but suggests numerous other substrates and substrate forms (Column 2, lines 32-40). While Clark does not specifically teach the claimed substrates, they were well known and routinely practiced as microarray substrates at the time the claimed invention was made as taught by Blackburn who teaches the preferred microarray substrate are selected from glass, glass beads, glass slides, polymers, polyethylene terephthalate, silicon, ceramic, metal oxides, clay, noble metal e.g. gold, silver, copper and having a thickness of approximately 1mm (Column 16, lines 40-59 and Column 17, lines 14-43). Hence, the claimed substrates were know and practice as functional microarray substrates. Therefore one of ordinary skill in the art would have been motivated to use any one of the claimed substrates with a reasonable expectation of success. One of ordinary skill would have been motivated to use any one of the claimed substrates based on the preferred teachings of Blackburn and based on available materials and/or experimental design.

The courts have stated with regard to physical and chemical homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904).

12. Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark (U.S. Patent No. 5,484,852, issued 16 January 1996).

Regarding Claims 34-35 and 37, Clark discloses a microarray (i.e. solid support, Abstract) comprising a diazotized tether group bound to a substrate and at least one polypeptide covalently bound to the tether (Column 10, lines 5-24). It is noted that the instant specification defines a microarray as "a device that employs the attachment of biomolecules, such as polypeptides, to a substrate." (¶ 34). Clark further discloses the diazonium comprises p-diaxoinumthiophenol salt (Column 5, lines 10-37) and teaches the diazo group is linked via an oxy group, a silyl group or the like (Column 4, lines 23-27). This clearly suggests a siloxy diazonium group as claimed. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the teaching of Clark and to use a siloxy group to link the protein via the diazonium. One of ordinary skill in the art would have been motivated to do so based on the teachings of Clark (Column 4, lines 23-27).

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
July 19, 2006